WOLTURNUS
Wheelchairs built for freedom

EU Declaration of Conformity

with the Medical Device Regulation (MDR) 2017/745

We,

Wolturnus A/S, Skalhuse 31, 9240 Nibe, Denmark - DK-MF-000025274

Name and Address of Manufacturer – Single Registration Number (SRN)

hereby, under our sole responsibility declare, that the product

Zitkite

Category Name

with model names and reference

Basic UDI-DI: 571382502986

Model
Zitkite

is in conformity with the Medical Device Regulation (MDR) 2017/745 as class I medical devices based on Annex VIII and the following common specifications (CS) and standards

DS/EN ISO 14971:2019, ISO 13485:2016

Standards

The intended purpose: The Zitkite is designed as an assistive device for windsurfing enthusiasts with reduced mobility. It is engineered to provide optimal support, stability, and mobility, enabling users to participate in watersports with maximum safety and comfort. Constructed from high-quality aluminum, the Zitkite ensures a lightweight yet strong and durable structure, while remaining easy to handle and transport. The product enhances the user's ability to move safely and maintain control on the water, promoting physical activity and improving overall quality of life.

This EU declaration of conformity was written according to Annex 4 in MDR, and all supporting documentation is retained at the premises of the manufacturer.

Manufacturer

March 31, 2025 - Nibe	Peter Libak, CEO	
Date and place of issue	*Name and position of authorized person*	*Signature of authorized person*